FACULTY OF PHARMACY

UNIVERSITAS SANATA DHARMA YOGYAKARTA

CERTIFICATE

THIS CERTIFICATE IS PROUDLY PRESENTED TO

Dr. apt. Sri Hartati Yuliani

as

SPEAKER

for participating in the

USD Pharmacy International Webinar Series 1

with the topic:

"Pharmaceutical Sciences - Biomedical & Clinical Sciences - Social - Behaviour Administration: The Colour of Pharmacy"

and is awarded **3 SKP IAI**

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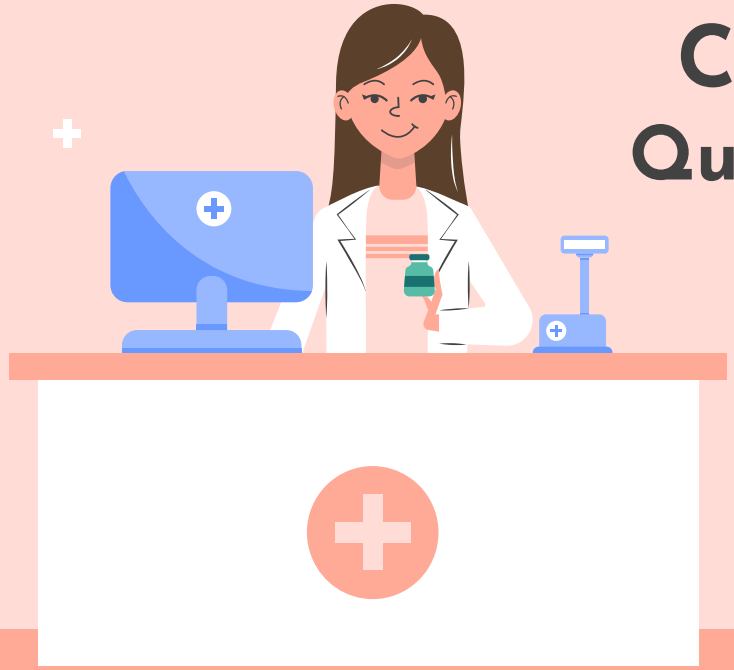


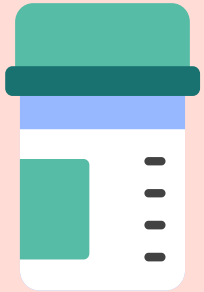
Compounding Practice: Quality of Extemporaneous Preparation

Dr. apt. Sri Hartati Yuliani

Outline

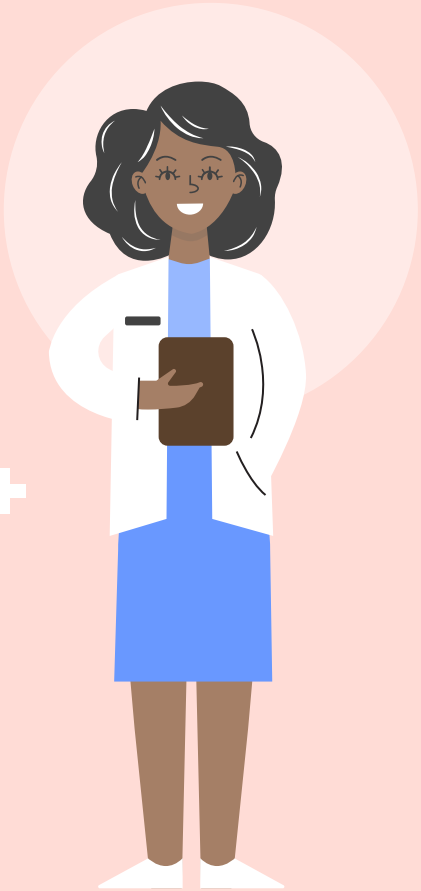
01 Introduction

Compounding is the manipulation carried out by pharmacists (pharmacist) on drugs or drug ingredients using traditional compounding techniques to produce appropriate preparations when commercial preparations are not available.



Compounding is high risk activities carried out by pharmacist

The risk come from the unlicensed product combined with the risk associated with pharmaceutical compounding process.



Pharmacists are responsible for ensuring that drug use is safe and effective

Gold standar for quality, safety, and efficacy is the licensed medicines

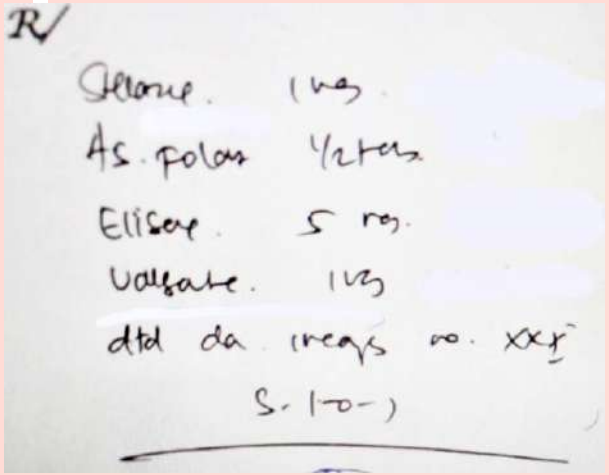
Why the quality of extemporaneous preparation is important

Most vulnerable patients

Error associated with the use of extemporaneous preparation

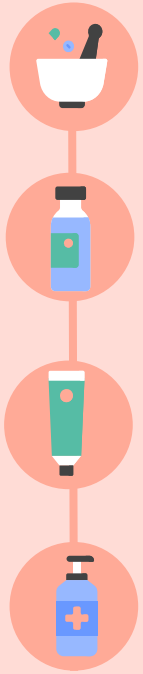
02 The quality of extemporaneous preparation

The quality of the Extemporaneous preparation



- The identity of drug
- Content uniformity
- Purity
- Maintaining the potency, therapy and appearance
- Drug release

The fitness for purpose



This product prepare for fit to the needs of individual patient

There is no licensed medicine that fully meets the clinical needs of the patients

Combining 2 or more drug/medicine

Appropriate dose for patient

Factors that can decrease the quality of extemporaneous preparation

Decreasing knowledge and skill formulation

No quality assurance during the preparation

The data of the product was limited

03 The quality of extemporaneous preparation in Indonesia

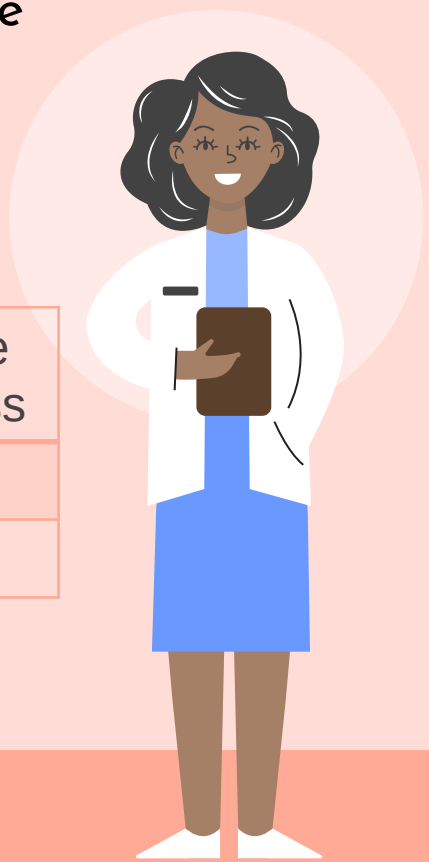
Potensial compounding error

Potensial compounding error

Divided powder – ambroxol HCl + Salbutamol sulphate

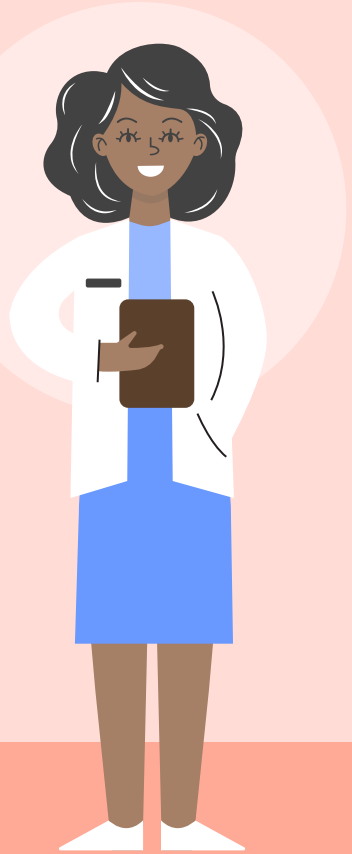
R/ Ambroxol HCl 30 mg ½ tab
Salbutamol sulphate 4 mg ½ tab
Mf pulv dtd no X

organoleptic	White crystalline powder, odorless	White crystalline powder, odorless
Particle size (µm)	11,08 – 28,93	
Moisture content (%)	6,04 ± 0,30	6,65 ± 0,46



Content uniformity

Ambroxol HCl (%)			Salbutamol Sulphate (%)		
172,35	53,38	145,32	144,73	61,68	105,82
81,85	174,89	115,88	100,44	131,73	99,65
107,87	146,20	99,88	109,84	113,69	85,84
153,75	186,27	123,02	140,02	129,56	98,14
130,13	145,22	83,85	124,31	114,72	75,31
167,73	130,57	60,70	139,26	105,36	98,02
171,53	121,34	98,85	140,97	106,99	100,17
84,80	152,76	124,27	98,57	107,95	98,67
140,91	138,76	92,18	158,94	104,66	82,96
94,42	133,17	148,87	112,38	99,66	112,19

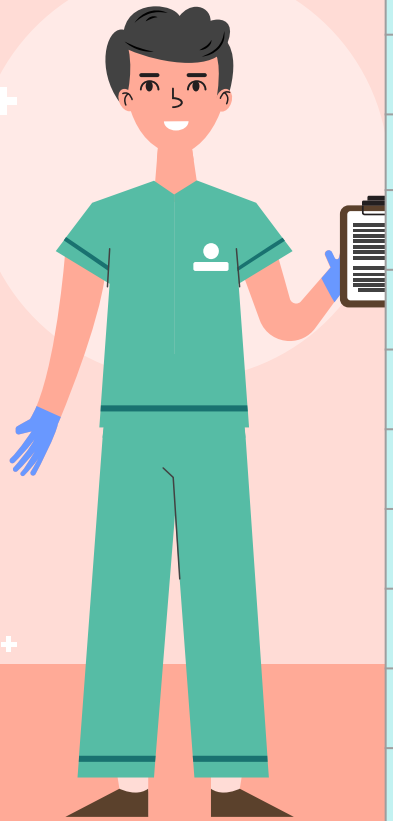


Divided powder – ambroxol HCl + tripolidine HCl + Pseudoephedrine HCL

R/ Ambroxol HCl 30 mg 1/3 tab
Alerfed® ½ tab
Mf pulv dtd no X

organoleptic	White crystalline powder, odorless	White crystalline powder, odorless
Particle size (µm)	6,69 – 24,49	
Moisture content (%)	5,10 ± 0,10	5,24 ± 0,11

Content uniformity



Ambroxol HCl(%)			Pseudoephedrine HCl (%)			Tripolidine HCl (%)		
83,04	89,67	59,58	79,78	89,19	67,02	115,23	208,89	124,86
93,28	82,99	78,07	81,74	72,66	82,40	171,73	159,15	148,60
77,38	68,96	53,71	76,80	72,04	60,93	116,82	154,65	138,53
80,68	71,71	65,95	82,22	70,47	77,81	113,58	129,63	166,52
97,11	89,03	86,91	80,35	82,47	88,28	124,37	143,17	194,54
60,10	97,57	64,40	65,04	78,16	79,30	88,04	152,45	154,33
84,16	89,53	64,28	89,10	80,70	75,12	152,67	108,86	159,45
87,27	80,93	63,46	84,14	81,10	73,04	121,06	142,87	153,92
115,15	79,13	71,11	88,88	81,08	74,50	186,33	151,83	146,52
66,00	76,92	66,90	70,50	79,27	74,80	153,72	153,99	153,45

04 How to improve the quality

Improve knowledge and skill of compounding

Update the current guidance and standart

Take a training about pharmaceutical compounding

Understand about formulation

Understand about principle of pharmaceutical stability and incompatibility

Assessment of risk and medication error potential

Do the screening for prescribing

- Permenkes 72 tahun 2016 : hospital pharmacy
- Permenkes 73 tahun 2016 : community pharmacy
- Permenkes 74 tahun 2016 : primary care

Determine the risk of preparation the product

- Clinical Risk
- Technical Risk

Managing the risk associated with the extemporaneous preparation

Clinical risk reduction

Technical Risk reduction - Preparation

Technical Risk reduction - Formulation

Clinical Risk Reduction

Identify extemporaneous preparation as high-risk therapy

Consider alternative therapies

Review all available evidence to support the use of preparation

Evaluate drug toxicity – consider therapeutic index

Document any problem and successful treatment for the future reference

Technical Risk Reduction - Formulation

Use validated formula where possible

Evaluate the data related the formulation (e.g stability, incompatibility, absorption, etc)

Use information resources

If no formula available, keep it simple using readily available, pharmaceutical-grade starting material, and standard vehicle

Restrict the shelf-life to limit degradation and spoilage (max 28 days if preserved and 7 days if unpreserved)

Technical Risk Reduction - Preparation

Prepare and use standard operating procedure for compounding preparation

Ensure facilities and equipment are appropriate and validated

Ensure all operatives are appropriately trained

05 Conclusion

Conclusion

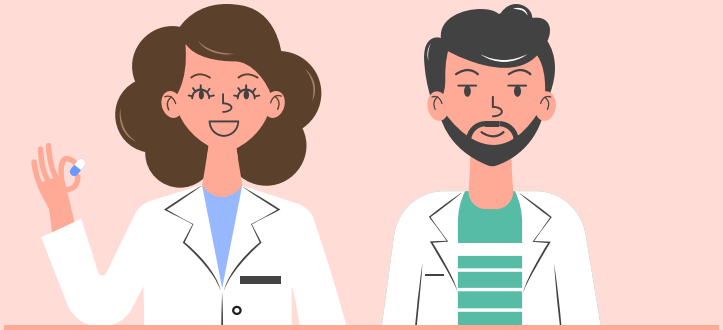
A

There are many extemporaneous preparation that do not meet the quality requirement

B

We can improve the quality of the extemporaneous preparation by following the current guidance of compounding practice

THANK YOU



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